

COMBINED CONSENT AND AUTHORIZATION TO PARTICIPATE IN A RESEARCH STUDY

**UNIVERSITY OF KENTUCKY
CHANDLER MEDICAL CENTER
MARKEY CANCER CENTER**

Study Title: 13-HN-24: A Phase II Study of Docetaxel, Carboplatin With and Without Low Dose Radiation as Induction Therapy in Locally Advanced Head and Neck Cancer

INVESTIGATOR INFORMATION: **Susanne Arnold, M.D.**
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 (859) 323-8043 (Day)
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WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about the treatment of head and neck cancer using a standard chemotherapy combination (Docetaxel/Carboplatin) with or without low dose radiation therapy (LDFRT). You are being invited to take part in this research study because you have locally advanced cancer of the head and neck. If you volunteer to take part in this study, you will be one of about 72 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Susanne M. Arnold, MD of the University of Kentucky, Department of Internal Medicine. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose(s) of this study is to evaluate the effects (good and bad) of standard chemotherapy (Docetaxel/Carboplatin) with and without low dose radiation. Docetaxel and Carboplatin are approved for the treatment of locally advanced squamous cell carcinoma of the head and neck.

The results of this study will be shared with the Kentucky Lung Cancer Research Program (KCLRP) who is providing financial support for the study, the Food and Drug Administration and other federal agencies, if required.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in the study if:

- You are under the age of 18
- You are pregnant or nursing a child

TO BE FILED IN MEDICAL RECORDS

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- You are currently taking any other investigational agents
- You have had an allergic reaction to the drugs used in this study (Carboplatin or Docetaxel) or similar compounds
- You currently have illnesses that would keep you from being in this study and following the study requirements such as: an active infection, congestive heart failure, unstable angina, cardiac arrhythmia, or psychiatric illness/social situations
- You are HIV-positive and receiving combination antiretroviral therapy

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of Kentucky's Markey Cancer Center. Treatment may be given on an inpatient or outpatient basis, and will last for 2 cycles (normally 21 days each).

You will need to come to the Markey Cancer Center for a pre-study visit and on Days 1, 2, 22, and 23 during treatment and at the end of treatment, usually between day 38 and 50. After that visit, you will begin definitive radiation or surgery between day 43 and 64, and after receiving definitive radiation treatment you will need to come in for an assessment. You will be asked to come in 4 to 6 weeks after definitive radiation or surgery for additional assessments. You will then be followed by your doctor for return of your cancer. If you agree to be in this study, you will be asked to volunteer for a total of about 3 and a half years.

WHAT WILL YOU BE ASKED TO DO?

Before you begin treatment (Pre-study visit)...

If not already completed within 6 weeks of starting the study:

- You will have a direct laryngoscopy or an indirect laryngoscopy, where a surgeon uses a camera or a small mirror to look down your throat at your cancer.

If not already completed within 4 weeks of starting the study:

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs, height and weight.
- You will have a Chest X-ray or CT scan of your chest.
- You will have a CT scan or MRI of your head and neck.

If not already completed within 2 weeks of starting the study:

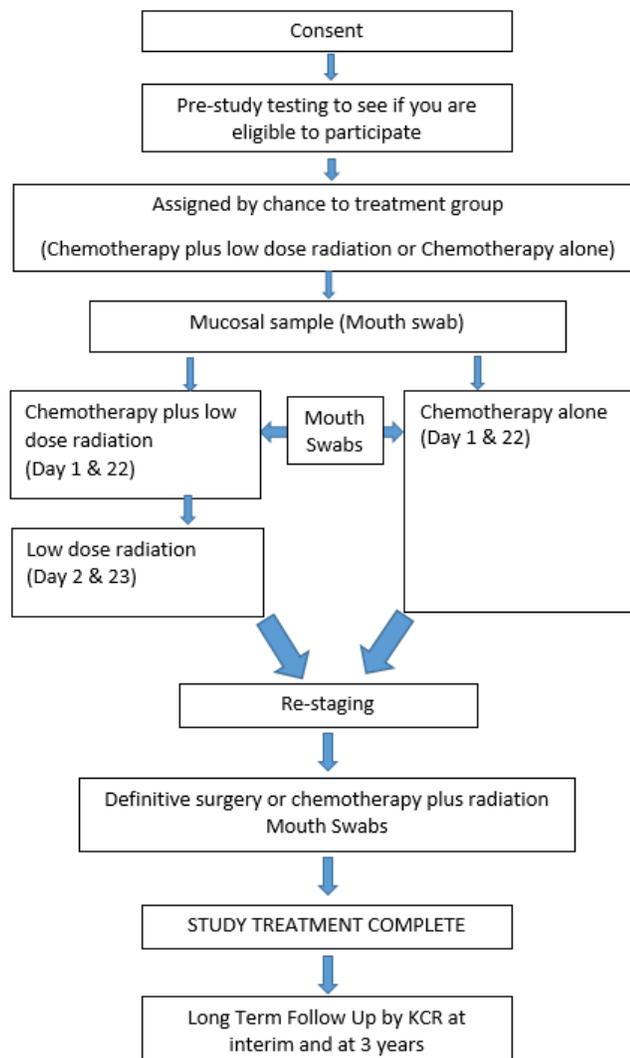
- You will have a blood sample drawn for routine laboratory tests including complete blood count and blood chemistries.
- If you are a female who is able to have children you will have a serum (blood) pregnancy test performed.

You will also be asked to fill out a form that helps us understand your quality of life during this study and to provide a mucosal sample of mouth cells.

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If the exams, tests and procedures above show that you are able to participate in the study, and you choose to take part, then you will be randomized (assigned by chance like flipping a coin) to one of two treatment arms: a) chemotherapy alone or b) chemotherapy plus LDFRT.

After you have been randomized to the study and before you start treatment, you will be asked to provide a mucosal sample. Mucosa refers to the lining of the cheeks. To provide a mucosal sample, you will be asked to rinse your mouth and a brush will be twirled against your inner cheek to dislodge cells. Next, your cheek will be gently scraped in the same region with a wooden spatula 10 times. Then your inner cheek will be swirled with a brush a second time. These mouth samples are for research purposes only, and will be sent to the research lab of Dr. David Orren and Dr. Tadahide Izumi for study of your cells' reaction to radiation. Your samples will be used for these studies and any leftover cells will be stored in this lab indefinitely. Only approved members of the research team will have access to your samples, and your samples will have a code number to protect your identity. Your samples will not be used for genetic testing.



If you are selected in the group that has chemotherapy only:

On Day 1

You will undergo the following procedures that are part of regular cancer care:

- You will receive the standard chemotherapy combination Docetaxel and Carboplatin.

You will also undergo the following tests and procedures that are for research purposes only:

- You will be asked to provide a mucosal sample.

On Day 22

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs, height and weight.
- You will have a blood sample drawn for routine laboratory tests including complete blood count and blood chemistries.
- You will receive a standard chemotherapy combination Docetaxel and Carboplatin.

If you are in the group that has chemotherapy plus LDFRT:

On Day 1

You will undergo the following procedures that are part of regular cancer care:

- You will receive a standard chemotherapy combination Docetaxel and Carboplatin with two small doses of radiation.

You will also undergo the following tests and procedures that are for research purposes only:

- You will be asked to provide a mucosal sample.

On Day 2

- You will be asked to provide a mucosal sample.
- You will receive two small doses of radiation.

On Day 22

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs, height and weight.
- You will have a blood sample drawn for routine laboratory tests including complete blood count and blood chemistries.
- You will receive chemotherapy using a standard chemotherapy combination (Docetaxel/Carboplatin) with LDFRT.

On Day 23

- You will receive LDFRT.

All subjects in both groups will undergo the following procedures after two cycles of induction treatment:

Day 38-50

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs, height and weight.
- You will have a blood sample drawn for routine laboratory tests including complete blood count and blood chemistries.
- You will receive an MRI or CT scan of your head and neck.
- You will receive a re-evaluation of your cancer by a surgeon (which may include a surgery called panendoscopy or indirect laryngoscopy, if needed).
- You will be asked complete a quality of life form.

You will then undergo definitive radiation therapy or surgery.

During Week 1 of definitive radiation therapy:

- You will be asked to provide a mucosal sample.

Within 4 to 6 weeks of definitive radiation therapy:

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs, height and weight.
- You will receive a Chest X-ray or CT scan of your chest.
- You will undergo a CT scan or MRI of your head and neck.

Long term follow up visit:

- You will receive a final assessment by the study doctor.

All procedures are being done as part of standard care except for the following procedures which are being done for research purposes:

- Mucosal samples
- Quality of life form administration
- We also will request a sample of your cancer tissue that was taken when you had your biopsy or surgery (if extra tissue is available) from the pathology laboratory that made your diagnosis. You will not have to undergo any additional biopsies or surgery to participate in this trial. This information and these samples will help researchers understand the effects of radiation and chemotherapy on your cancer and will be compared to your mucosal samples. These samples will not be stored long-term or used for other investigations other than this study. No identifiers

or private health information will be given to investigators who study your tumor and the investigators will not be able to identify you.

- We will also request the radiation treatment planning pictures (CT scans) of your head and neck to study the region of the throat that received radiation to better understand how your cells react to radiation. No identifiers will be given to investigators that study these images, and the investigators will not be able to identify you.

Women who can become pregnant and men must agree to use adequate contraception (hormonal or barrier method of birth control or abstinence) prior to study entry, through the duration of active treatment and for 4 months after completion of chemotherapy and radiation administration, both induction and definitive, if applicable. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately. Men treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of active study treatment, and for 4 months after completion of chemotherapy and radiation (both induction and definitive) administration.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

Risks and side effects related to the radiation include those which are:

Likely

- Tanning, redness, or darkening of skin in treatment area
- Rash, itching or peeling of skin
- Temporary hair loss in the treatment area
- Temporary fatigue

Possible Side Effects of Carboplatin:

COMMON, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, more than 20 and up to 100 may have:
<ul style="list-style-type: none">• Hair loss• Vomiting, nausea• Infection, especially when white blood cell count is low• Anemia which may cause tiredness, or may require blood transfusions• Bruising, bleeding• Belly pain

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, from 4 to 20 may have:
<ul style="list-style-type: none">• Diarrhea, Constipation• Numbness and tingling in fingers and toes• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

RARE, AND SERIOUS In 100 people receiving Carboplatin, 3 or fewer may have:
<ul style="list-style-type: none">• Changes in vision• Changes in taste• Damage to organs which may cause hearing and balance problems

Possible Side Effects of Docetaxel

COMMON, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, more than 20 and up to 100 may have:
<ul style="list-style-type: none">• Swelling of the body• Hair loss• Change in nails• Rash, itching• Vomiting, diarrhea, nausea• Sores in mouth which may cause difficulty swallowing• Infection, especially when white blood cell count is low• Anemia which may require blood transfusions• Tiredness• Numbness and tingling of the arms and legs• Fever• Absence of menstrual period• Swelling and redness of the arms, leg or face• Pain• Watering, itchy eyes

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, from 4 to 20 may have:
<ul style="list-style-type: none">• Severe skin rash with blisters and peeling which can involve inside of mouth and other parts of the body• Belly pain• Bruising, bleeding• Liver damage which may cause yellowing of eyes and skin• Kidney damage which may require dialysis• Scarring of the lungs• Blood clot which may cause swelling, pain, shortness of breath• Abnormal heart rate• Shortness of breath, wheezing• Chest pain

RARE, AND SERIOUS In 100 people receiving Docetaxel, 3 or fewer may have:
<ul style="list-style-type: none">• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat• Liver damage which may cause yellowing of the eyes and skin

Blood Draw: soreness, bruising, pain, infection, possible fainting, bleeding.

CT Scans: Each CT scan will give a radiation dose greater than that from typical natural background exposure, but less than the limit for radiation workers and well below the levels that are considered to be a significant risk of any harmful effects.

MRI exam:

LIKELY:

- Anxiety/stress
- Claustrophobia
- Discomfort
- Discomfort of noise level when having the MRI

RARE, BUT SERIOUS:

- Injury related to the presence of metallic or surgical implants or metal pieces in the body and the MR magnet; it is important that you let the MRI team know about whether you have these before the MRI procedure.

Possible Risks of Infusions:

You will receive study drug intravenously, which means you will receive it directly into your vein. This may cause the following problems:

- irritation of the vein; your skin near the vein could become warm, swell, hurt, or get red
- damage to your vein
- damage to the skin or tissue around the injection site
- increase or decrease in electrolyte levels (the amount of certain salts and other chemicals in your blood), causing health problems

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- a blood clot or an air bubble could form, which could block a blood vessel in another part of your body

Reproductive risks:

You should not become pregnant or father a baby while on this study because the treatment used in this study may involve a risks to you (or your embryo or fetus if you become pregnant) which are currently unforeseeable. Women should not breastfeed a baby while on this study. It is important that you understand that you need to use birth control while on this study and for 4 months after your last treatment. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. Some of the drugs used in the study may make you unable to have children in the future.

If you or your partner becomes pregnant anytime during the study or within 4 months after stopping the study drug, you **MUST** immediately tell your study doctor. The study doctor must then report the outcome of the pregnancy to the Sponsor (and/or the FDA).

For more information about risks and side effects, ask your study doctor.

There is always a chance that any medical treatment can harm you, and the investigational treatment in this study is no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There may be no direct benefit to you for participating in this study. The growth of your cancer may be slowed as a result of your participation in this study; however, that result cannot be guaranteed. Your participation in this study could help advance medical research and the information from this research may help other people with cancer.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, the following types of alternative therapy are available: other chemotherapy, radiation or palliative therapy, which is therapy that provides relief of symptoms of your cancer. You do not need to participate in this study to receive treatment for your cancer.

You may talk with your study doctor about these and other options before you agree to enter the study, and about other options that may become available during the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

Medicare, or Medicaid will pay medically necessary costs (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid at 1-800-635-2570. **A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs.** Some health plans will not pay for some costs of people taking part in clinical trials. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research. Neither you nor your insurance company will be billed for the collection of mucosal samples, the quality of life assessments or the 3 year follow up assessment. These costs will be paid by the sponsor KCLRP.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. At the University of Kentucky, data is stored at the Markey Cancer Center in locked facilities, and with limited access to records by designated research staff.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include:

- The University of Kentucky Institutional Review Board
- Representatives of the U.S. Food and Drug Administration as required by law
- Representatives of the National Cancer Institute (NCI)
- Representatives of the Kentucky Cancer Registry

- Authorized representatives of the University of Kentucky, UK Hospital, and Markey Cancer Center and the Kentucky Lung Cancer Research Program (KCLRP)

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study, and the study medication will no longer be provided by the investigator. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

If you are a female of childbearing potential, your participation in this study may be discontinued if you become pregnant or suspect you may have become pregnant.

If you decide to leave the study, please contact Susanne Arnold, MD or one of the study associates who will tell you what you should do before leaving. You may be asked to return to the clinic for follow-up care, if necessary. You may be asked to have any laboratory tests, or physical examinations that the study doctor feels are necessary. Until your permission is withdrawn, additional information may continue to be taken from your medical records for study follow-up purposes.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not be allowed to take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call **Susanne Arnold, M.D. at (859) 323-8043** immediately. If you should have an emergency after 5pm during the week or on the weekend, please contact the **UK Paging Operator at (859) 323-5321** and ask to page Susanne Arnold, MD. She will determine what type of treatment, if any, that is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm will be your responsibility. It is possible that these costs may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); or may be paid by Medicare or Medicaid if you are covered by Medicare, or Medicaid (if you have any questions regarding Medicare/Medicaid coverage

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you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.

A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study. There is a chance that the mucosal samples that you are donating under this study may be used and may have some commercial value. Should your donated mucosal sample(s) lead to the development of a commercial product, the University of Kentucky will own it and may take action to patent and license the product. The University of Kentucky does not intend to provide you with any compensation for your mucosal sample donation nor for any future value that the mucosal samples you have given may be found to have. You will not receive any notice of future uses of your mucosal sample(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Susanne Arnold, M.D. at (859) 323-8043 or your study coordinator at (859)257-3379. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data/tissue/specimens/blood collected from you may be shared with other investigators in the future. If that is the case the data/tissue/specimen/blood will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

The Kentucky Lung Cancer Research Program (KCLRP) is providing financial support and/or material for this study.

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A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic Information (Example: Sex, race & age, etc.)
- History and diagnosis of your disease
- Specific information about treatments you have received
- Past and present medical records pertaining to your health condition
- Your entire research record
- Information about other medical conditions that may affect your treatment
- Medical data, including physical examinations, laboratory test results, tumor measurements, CT scans, MRIs, X-rays, photographs of radiation therapy target areas, and pathology results
- Information on side effects (adverse events) you may experience, and how these were treated
- Long-term information about your general health status and the status of your disease
- Mucosal, tissue and/or blood samples, associated data related to the analysis of the samples

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- Authorized representatives of the University of Kentucky, UK Hospital, and Markey Cancer Center
- Representatives of the Kentucky Cancer Registry
- Representatives of the U.S. Food and Drug Administration (FDA)
- Kentucky Lung Cancer Research Program (KCLRP) and their representatives
- The National Institutes of Health and its affiliates including the for Human Research Protections (OHRP) and the NCI (National Cancer Institute) and their affiliates

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws, which were made to protect you.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**

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- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**
- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If you revoke the authorization:

- You must send a written letter to: Susanne Arnold, M.D. c/o Markey Cancer Center Clinical Research Organization, cc140 Markey Cancer Center, 800 Rose Street, Lexington, KY. 40536-0093 to inform her of your decision. In that letter you should describe what you want to revoke:
 - If you do not want to participate in future follow-up
 - If you do not want to allow the use of your current information
 - If you want to have samples that have not already been used destroyed
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You may not be allowed to participate in the study.

If you become pregnant anytime during the study or within 4 months after stopping the study drug, you must inform the study doctor. The study doctor must then report the outcome of the pregnancy to the sponsor and the FDA.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

Signature of person agreeing to take part in the study

Date

Printed name of person agreeing to take part in the study

Name of [authorized] person obtaining informed consent

Date

Signature of Principal Investigator or Sub/Co-Investigator